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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/552,886
Filing Date: November 18, 2005
Appellant(s): DORN, JURGEN

Todd Wight
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8-26-2009 appealing from the Office action mailed 10-29-2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,607,551	Sullivan et al.	8-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-19 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. (US 6,607,551).

Regarding claims 1, 3, 5, 10, 11, 19, 28, Sullivan discloses a delivery system and a method of loading a self-expanding stent into a delivery sheath. Said system and method include providing a self-expanding stent graft 34 (Column 1, Lines 18-27) comprising a stent matrix and graft layers of covering lining the inside and outside of said stent matrix. (Column 1, Lines 18-27) Although Sullivan does not explicitly state that the inner and outer layers of graft material are bonded to one-another, it would have been obvious to one of ordinary skill in the art to have the inner and outer layers of graft material be bonded to one-another in order to hold the stent graft together as a single entity. The stent matrix has apertures. (Figure 2B) It would have been obvious for said bonding between the luminal and abluminal coverings to occur across the stent matrix through said apertures since the covering layers may contact one another through said apertures. There is a stent pusher 30A (Figure 3A) that has radially outwardly extending protrusions 38 distributed along the length of the stent graft 34. Said stent pusher 30A is also considered an inner catheter 30A. The stent graft 34 is compressed into a delivery configuration onto the stent pusher 30A such that the protrusions 38 engage the inner surface of the stent graft 34. (Column 3, Lines 19-51)

Sullivan does not speak directly to the issue of compressing the stent radially inwardly such that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope. The disclosure of Sullivan is primarily concerned with an embodiment wherein the stent is uncovered. Sullivan does,

however, teach that the retention means disclosed therein is compatible with a covered stent, and further teaches that the protrusions may merely be in frictional engagement with the inner periphery of the stent. (Column 1, Lines 25-27 and Column 6, Lines 3-4) By compressing the stent graft 34 onto the protrusions 38, the protrusions 38 inherently deform the covering material. It would have been obvious to one of ordinary skill in the art at the time of the invention to compress the stent such that the protrusions do not extend outwardly through the covering layer into the luminal envelope in order to prevent damage to the stent since Sullivan teaches that frictional engagement alone is sufficient to retain the stent.

Sullivan discloses that an endwise force is imposed on the stent pusher 30A so that the covering material transfers the pushing force from the protrusions 38 of the stent pusher 30A to the stent matrix to advance the stent 34 into the sheath 40. (Column 12, Line 63 through Column 13, Line 20) Sullivan also discloses that a force is imposed on said stent pusher 30A, transferring said force to the stent graft 34 to move said stent graft relative to the sheath 40, thereby deploying said stent graft 34.

Regarding claims 2, 7, 15, and 16, Sullivan discloses that the protrusions comprise a series of helically arranged locking rings. (Column 11, Lines 10-11) Arranged helically, the protrusions comprise a wire bonded helically about an outer surface of the distal end of the stent pusher. (Figure 3A) In this configuration, the stent pusher is capable of being withdrawn from the lumen of the stent by unscrewing the stent pusher relative to the stent lumen.

Regarding claims 4, 6, 12, and 18, the stent matrix comprises nitinol. (Column 5, Lines 44-48) Sullivan does not discuss the material used to form the covering layers of the stent graft. It would have been obvious to one of ordinary skill in the art at the time of the invention to have the covering layers comprise ePTFE or polytetrafluoroethylene since it was a known material used in the formation of covering layers of stent grafts.

Regarding claim 8, 17, and 22, Sullivan does not disclose that the sheath has a tapered distal tip. It would have been obvious to one of ordinary skill in the art to provide the sheath with a tapered distal tip in order to better retain the stent within said sheath. Said tapered distal tip would narrow to a size appropriate to receive a guidewire.

Regarding claim 9, Sullivan discloses that the inner catheter has a tapered distal tip positioned distal of the sheath. (Figure 7)

Regarding claims 13, 14, and 26, it was well known to provide markers on such delivery implements to allow a physician to accurately locate important elements. It would have been obvious to provide a plurality of markers arranged circumferentially about a proximal and distal end of the stent in order to allow a physician to accurately determine the location of the stent for delivery. It would have been obvious for said markers to comprise tantalum since tantalum was a material commonly used for fabrication of medical markers.

Regarding claims 16, 23, and 27, Sullivan does not disclose that the inner catheter and wire comprise stainless steel. It would have been obvious to one of ordinary skill in the art at the time of the invention to have said elements comprise

stainless steel since it was a known material from which to form medical instruments designed to be inserted into the body.

Regarding claim 21, the pusher has an outside diameter smaller than a luminal diameter of the stent.

Regarding claim 24, the inner catheter defines a guidewire lumen. (Figure 3A)

Regarding claim 25, rapid exchange delivery systems wherein a guidewire lumen is only in a distal zone of the delivery system were well known at the time of the invention. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Sullivan by making the delivery system a rapid exchange system such that the guidewire lumen is only in a distal zone of the delivery system in order to allow the system to be quickly exchanged for a new catheter system without having to insert a new guidewire to the delivery site.

Regarding claims 28-30, Sullivan discloses withdrawing the outer sheath to deploy the stent at the stenting site. (Column 5, Lines 10-20) Said withdrawing step includes moving the proximal end of the outer sheath in a proximal direction, such that a tip of the outer sheath stretches and slides over an abluminal wall surface of the stent.

Regarding claim 31, the outer sheath 40 of Sullivan runs along the length of the inner catheter 30A and, as such, is withdrawn as a unit from the proximal end. It would have been obvious to one of ordinary skill in the art to provide an outer sheath only over the distal end retaining stent 34 and using a pull wire to withdraw said modified outer sheath since these two methods of withdrawing a sheath are functional equivalents.

Regarding claim 32, the inner catheter is withdrawn from the lumen of the stent graft following the expansion thereof to an expanded diameter.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. (US 6,607,551) in view of Grosjean et al. (US 5,619,878).

Regarding claim 20, Sullivan teaches that the protrusions are helically arranged and that the stent graft is compressed onto said protrusions such that the luminal covering layer is deformed by said protrusions, but does not discuss withdrawing the stent pusher from the stent graft by unscrewing it. Grosjean teaches that it was well known to withdraw an inner element having a helical protrusion from a complimentary tubular element by unscrewing it. (Column 5, Lines 48-65) It would have been obvious to one of ordinary skill in the art at the time of the invention to withdraw the stent pusher from the stent graft by unscrewing it as taught by Grosjean.

(10) Response to Argument

With regard to claims 1, 3-6, 8-14, 16-19, and 21-32, Appellant relies upon one or both of two central arguments. In the first argument, Appellant holds that Sullivan fails to disclose a covered stent in combination with the retention means disclosed therein. In the second argument, Appellant argues that even Sullivan does disclose a covered stent in combination with said retention means, there is no teaching for the claimed feature that the protrusions deform the covering without extending into the luminal envelope of the stent framework.

In response to the first argument, holding that Sullivan fails to disclose covered stents in combination with the retention means disclosed therein, Examiner points to the passage in Column 1, Lines 25-27, reading, "As used herein, however, the term "stent" is a shorthand reference referring to a covered or uncovered such stent." Following this definition, Sullivan discloses several retention means comprising protrusions that engage stents. For example, see the passage extending from Column 5, Line 63 to Column 6, Line 4, reading:

> Preferably, stabilizer 30A or 30B comprises a surface element underlying stent 34 from proximal end 17 to distal end 15 of the stent along low-column-strength segment 18 and adapted for such engagement of the stent inner periphery. For example, the surface element may comprise a high friction surface, such as covering 138 as shown in FIG. 2A, or a plurality of protuberances 38, such as the rings shown in FIG. 2B. Protuberances 38 may also be in frictional engagement with the inner periphery of stent 34.

Since Sullivan explicitly states that use of the word "stent" as used in the disclosure is a shorthand reference meaning a covered or uncovered stent, it seems clear from this passage that an embodiment wherein protuberances 38 are in frictional engagement with the inner periphery of a covered stent is within the scope of the Sullivan disclosure.

In the second argument, Appellant holds that even if Sullivan teaches use of a covered stent positioned over a retention means comprising protrusions, Sullivan fails to teach that the protrusions deform and extend into the inner covering layer, but do not extend into the luminal envelope of the stent framework. In response, Examiner first notes that Sullivan discusses compressing a stent onto the retention portion of many embodiments of the delivery apparatus throughout the specification. (See at least

Column 3, Lines 10-15, 59-67 and Column 4, Lines 3-8) Although it is not directly addressed in the particular embodiment relied upon for the present rejections, the process of compressing a stent onto a stent retention portion of a delivery apparatus was a well-known and standard practice for preparing both covered and uncovered stents for endoluminal delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to compress the covered stent of Sullivan onto the retention portion of the device in order to load the stent onto the device and prepare it for delivery. Upon compression onto the retention portion of the apparatus, the protrusions will deform into the inner covering layer (typically a relatively flexible polymer) to at least some degree. The extent to which the protrusions deform into this layer is a function of the size and shape of the protrusions, the material used for the covering layer, and the force used to compress the stent. It would have been obvious to one of ordinary skill in the art to size the protrusions such that they do not extend entirely through the inner covering layer to the metal framework of the stent in order to reduce structural damage to the covered stent.

With regard to claims 2, 7, and 15, Appellant submits that Sullivan fails to teach a protrusion that extends as a spiral around the pusher/inner catheter. In response, Examiner notes that Sullivan discloses that the protrusions comprise a series of helically arranged locking rings. (Column 11, Lines 10-11) Helically arranging the locking rings such as those shown in Figure 3A would result in a protrusion that extends helically around the pusher/inner catheter. In this case, the stent would be capable of being removed from the retention portion by unscrewing the stent.

Regarding claim 20, Appellant argues that the rejection over Sullivan in view of Grosjean is improper, submitting that Sullivan and Grosjean are not properly combinable since they are drawn to dissimilar subject matter (a stent delivery system and a corrugated metal pipe), and further, since Sullivan teaches away from moving the stabilizer relative to the stent. In response, Examiner notes that Grosjean is relied upon soley for its teaching that wherein a cylindrical body is retained over a helical protrusion on a second body, one may unscrew said bodies relative to one another. This teaching is applicable in the Sullivan system as a means by which to separate the stent from stabilizer during delivery or prior to delivery for purposes such as replacing or repositioning the stent on the stabilizer. Sullivan discloses a system wherein a covered stent is maintained on a stabilizer having a helical protrusion that extends at least somewhat into the stent's covering such that it the stent capable of being unscrewed from the stabilizer. It would have been obvious to one of ordinary skill in the art at the time of the invention to unscrew the stent relative to the stabilizer as taught by Grosjean in order to remove the stent from the stabilizer to deliver the stent or replace it on the stabilizer prior to delivery.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Eric Blatt

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